REMARKS

New claims presented herein correspond to prior claims as follows:

Claims 64-83 are based on Prior Claims 37-50 and 61.

Claims 84 et seq. are based on Prior Claims 51-58 and 60-63.

As indicated previously, support for prior claims is as follows: Prior Claims 37 *et seq.* (as well as new Claims 64-91) find support in the specification as follows: Substrates (of claims 37, 44 and 51) are recited to include *inter alia* polyurethanes, at page 13 line 4 , and include silicone polymers at page 12, line 18 *et seq.* Graft copolymers (of claims 37, 47 and 51) are supported by page 17 line 20. At page 8 the graft (co)polymer (of claims 40, 47, and 54) is described as a tie coat to adhere to additional successive layers. In addition, the graft copolymer (of claims 41, 48, and 55) provides moisture absorption or lubricity; and can (as in Claims 42, 49 and 56) provide functional groups to attach physiologically or pharmacologically active agents; and or act as a drug depot permitting the delivery of drugs from the grafts.

Additional portions of the specification support the new claims 64 *et seq.* the specification describes specific embodiments, as follows: Specification page 20 lines 10-19 and Example 1 at page 22 and Example 7 describe preparation of a coating comprising acrylamide, and dimethylacrylamide, in the presence of polyvinylpyrrolidone 64. Specification page 20 lines 20 *et seq.* and Example 2 at page 23 and Example 3 at page 25 provide additional support for an embodiment in which the coating is formed of acrylamide, polyethylene glycol acrylate, in the presence of polyvinyl pyrrolidone. Also please see the Examples for substrates comprising PVC [Example 9] and silicone, polyolefin and polyurethane. Also please see page 21 lines 8-14 and Example 7 for

coatings formed of polyurethane, acrylic polymer, epoxy polymer, PET, while page 21 lines 20 *et seq.* describe an embodiment in which the coating is formed from hydroxyethylmethacrylate in the presence of PEG. Page 21, line 20 ***et seq.*** also describes a third successive layer thereto in claims 67, 77, 86 and 87.

Comparison of the claims to the above designated support will reveal that claims 37-91 are all supported by the originally filed application, in the sense of written description of Section 112.

The U.S. PTO alleges, in the ADVISORY ACTION, that the specification provides support for specific monomers within the genus of pyridine and piperidine "but there is no indication in the original disclosure that the broad genus of pyridine or piperidine could be used..." This statement underscores the danger of rephrasing claim language: The words "pyridine" and "piperidine" identify unique individual compounds, i.e., identify ***species.*** As indicated previously, The claims do not recite use of "piperidine" or use of "pyridine". The issue is moot with respect to independent claims 64 and 87 (and claims dependent thereon).

Applicants respectfully traverse the rejection(s) under 35 U.S.C. 102(b). Applicants reiterate the comments which appeared in the response to the FINAL ACTION of November 24, 2006 immediately below and then address the Examiner's commentary in the ADVISORY ACTION in the last paragraph hereof.

The error in the PTO reasoning is two-fold. To attempt to satisfy the MPEP requirement that an anticipatory reference must provide description of each and every element of the claim under examination, the PTO must eliminate recitations from the rejected claims and disregard express description in Michal et al. The PTO states,

> Regarding claim 37, Michal et al. anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). Note the substrate **is not defined as being limited** to only one layer or one type of material. Therefore, the **substrate in its broadest reasonable interpretation could include** a two-layered material. Michal et al. teach a medical device **formed of a substrate formed of the combination of a metal device (col.5, 1.42-44) containing a base coat over top of the metal device.** Therefore, the base coat and metal device combined teach the substrate as claimed in Applicant's claim 37. The base coat comprises a binding component, which is formed of a isocyanate compound (col.8, 1.14-31), such as the urethane-acrylate taught in example 4 in column 16, lines 49-51**). Thus, the substrate comprises copolymers of polyurethane.** A plurality of monomer molecules are directly graft polymerized on at least one of the surfaces of the substrate, forming a top coat thereon (col.11, 1.5-10). The top coat is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an acrylamide, N,N-dimethylacrylamide, and mixtures thereof (col.8, 1.1-6). [Office Action of August 31, 2006, paragraph 7.]

While the PTO relies upon the figure as an anticipation, it is clear that the literal terms used by the PTO, to rely upon the Michal Figure, are inconsistent with the Michal description at column 2 lines 5 et seq. The Examiner's interpretation of the Michal Figure does not find an enablement in the Michal disclosure at column 2. The word "could" in the first sentence of the USPTO reasoning, ***excerpted above,*** supports the view that the grounds of rejection based on Michal is speculation. Speculation does not constitute written description and does not satisfy the statutory meaning of 'described', In re Wiggins, 488 F.2d, 179 USPQ 421 (CCPA 1973); In re Arkley, 172 USPQ 524 (CCPA 19720). Accordingly, there is no support for a rejection of claims 37, 44 and 51 over the Michal Figure.

The following excerpts are taken from certain of the cites to Michal in the Office Action(s) and are discussed in connection with Claims 37, 44 and 51. In applicants'

view, none of the actual text relied upon by Examiner satisfies the MPEP requirements of an anticipatory reference. Please see MPEP Section 2131: It requires a one to one correspondence of claim elements to those of a prior allegedly anticipatory device.

The Patent Office has relied upon the description at Michal Example 4 [column 16, of Michal]. The description at Example 4 [column 16] describes a stent coated with a urethane-acrylate, applied by dip coating [column 16 line 58] and subsequently applying a top coat of 1.0% peptide, such as albumin as a " top coat solution" [column 16 line 64]. That section does not comport with the requirements of an anticipatory reference with respect to Claim 37. Please see MPEP Section 2131: It requires a one to one correspondence of claim elements to those of a prior allegedly anticipatory device.

The Patent Office also relies upon the Michal description at column 8 line 1-6. The Michal description at column 8 lines 1-6 [sentences in a paragraph bridging column 7 and column 8] recites:

> In another embodiment, the binding component...Exemplary of the hydrophilic agent are a (co)monomer selected from.....and N-(3-aminopropyl)methacrylamide; or a polymer of at least one of said (co)monomers co-polymerized with hydropyile monomers, ...from the group consisting of acrylamide, di-methyl acrylamide and N-vinyl pyrrolidone or a peptide

The Patent Office also relies upon the Michal description at column 8 line 14. The Michal description at column 8 recites:

> In another embodiment, the binding component is an isocyanate compound and the top coat is a compound containing hydroxyl or amine groups. [Column 8 lines 14 et seq.]

The Examiner further alleges: The linking agent comprises a monomer or derivative selected from acrylamide or N,N-dimethylacrylamide (col.9, 1.46-56). Review of the reference reveals that it states at column 9 line 46 et seq.

> Primary amine groups, hydroxyl, thiol, or carboxy ... can be added to liposome or microsponge linking agents ...For example, compounds having the desired functional groups, such as monomers such as hydroxyethylmehacrylate having a hydroxyl functional group and n-(3-aminopropyl)acrylamide having an amine functional group, can be introduced into the bead composition during synthesis of the microsponges....the process used for functionalizing the microsponges with hydrophilic monomers such as...n-(3-aminopropyl) methacrylamide hydrochloride...

The Examiner also relies upon column 5 lines 34-41 , that portion of the references recites:

> The coating can be applied to any device having a polymeric surface ... or a metal device ... for example, the catheter components may be formed of high density polyethylene, polyethylene terephthalate, and polyolefinic ionomers...

That portion of Michal also fails to anticipate Claim 37; applicants rely on the MPEP Section 2131 for the requirements of an anticipatory reference.

The Examiner further relies upon Column 11 lines 5-10 of Michal which speaks to the ..." a ... coat... on the surface of the coating available to graft the agent of the top coat." In order to anticipate the reference must describe each and every element of the claim. MPEP Section 2131. Michal does not describe each an every element of e.g. prior independent Claims 37, 44, 51 (or current independent Claims 64, 83 or 74) and thus does not describe those same elements which are incorporated into claims dependent from claims 37, 44 and 51.

With respect to dependent claims the PTO alleges:

> Regarding claims 38-39, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).
>
> Regarding claims 40 and 42, the coating further comprises a linking agent that is placed between the substrate including the base coat and the therapeutic containing layer (col.2, 1.62-64). In this embodiment the linking agent is the plurality of monomer molecules and the therapeutic containing layer is the additional layer. Therefore, the coating represented by the linking agent layer of Michal et al serves as a tie coat to adhere the additional layer and has functional groups to attach or bind physiologically or pharmacologically active gents.
>
> Regarding claim 41, the top coat is a hydrophilic agent made of acrylamide or N,N-dimethylacrylamide so inherently absorbs large quantities of water to provide moisture absorption or of lubricity.
>
> Regarding claim 43, the coating comprises a drug depot permitting the *delivery of drugs form the graft polymer coating (col.4, 1.10-65).*
>
> *Regarding claims 58 and 61, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).*
>
> *Regarding claims 44 and 51, Michal et al anticipate a medical device comprising a substrate constructed and arranged for insertion into a patient and having at least one lumen, said substrate having an exterior surface and interior luminal surface defining the lumen (Figure 1). The substrate comprises polymers or copolymers of polyolefins or polyamides (col.5, 1.34-41). The substrate has either a coating comprising a base coat and top coat system or a coating comprising a coating comprising a grafting component blended with the hydrophilic agent directly grafted to the substrate (col.11, 1.17-21 and col.12, 1.4-7). In the embodiment in which the coating comprises a base coat and top coat* system, the base coat is a plurality of monomer molecules directly graft polymerized on the surface of the substrate, forming a coating thereon, wherein said coating on said substrate is a polymer or copolymer or a derivative of said polymer or copolymer formed from a monomer or derivative thereof selected from the group consisting of an alkylacrylate such as methacrylate (col.8, 1.28-31 and 1.50-54).
>
> Regarding claims 45-46 and 52-53, the medical device is a catheter, guide wire or medical instrument (col.2, 1.10-12), and the catheter is specifically a PTCA catheter (col.5, 1.53-56).
>
> Regarding claims 47 and 54, in the embodiment in which the coating is the base coat of the coating system the top coat forms an additional layer and the base coat serves as a tie coat to adhere the additional layer to the substrate.
>
> Regarding claims 48 and 55, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the

> coating absorbs large quantities of water to provide moisture absorption or of lubricity.
>
> Regarding claims 49 and 56, in the embodiment in which the coating is the base coat of the coating system the top coat is a physiologically or pharmacologically active agent that is bonded to the base coat by the functional groups of the base coat.
>
> Regarding claims 50 and 57, in the embodiment in which the coating is a hydrophilic coating directly grafted to the substrate, the coating comprises drugs for delivery within the body, so the coating is a drug depot.
>
> Regarding claims 59-60 and 62-63, a portion or the entire surface of the interior surface, exterior surface or both of the substrate are coated (col.14, 1.1-20).

Michal does not anticipate the dependent claims as Michal does not provide description, of all of the recitations in claims 37, 44 and 55 which per force of law are incorporated into claims dependent therefrom. Withdrawal of the rejections for anticipation is respectfully solicited.

In the Advisory Action of November 2006, the USPTO refers to a definition of the term "substrate". The term "substrate " appears in each of the independent claims. The USPTO also recognized that a Markush group [in each of the prior independent claims] recited the components of any "substrate". In applicants' view, the divergence in subject matter between the Michal reference and the claims that appear herein and the claims previously at issue, requires the conclusion that Michal does not satisfy the case precedent which interprets the word described in Section 102 or evidence which is required by Section 103. Cf. MPEP Section 2131.

In applicants' view the USPTO position is in error and that error is reflected by two positions advanced by the Examiner.

In the Advisory Action of November 24,2006 [page 4], the Examiner stated

"The broad term substrate means an underlying support according to the Merriam-Webster Dictionary. This does not limit a substrate in any manner other than being something that another layer or coating can be applied. Therefore, the metal layer and base coat of Michal et al meets the limitation of "substrate" as claimed in Applicant's claims." At paragraph 7 of page 7 of the Final Action of August 31, 2006 the USPTO states, "Note the substrate is not defined as being limited to only one layer or one type of material.. Therefore, the substrate in its broadest reasonable interpretation could include a two-layered material."

The Examiner fails to refer to the recitations in the rejected claims which refer to the "substrate". Instead of using the reference for what the reference in fact describes, the position of the USPTO is decapitating the descriptions expressly referred by Michal as independent embodiments and dissecting the embodiments and reconstructing to assert "description" which is not that of the actual text of Michal.

Lastly applicants note that the USPTO dissects mutually exclusive embodiments in the reference, reassembles components of those embodiments, and attempts to formulate species to allege anticipation. Please see pages 8 et seq. of the Final Rejection of August 31, 2006. This is consistently undertaken with lack of regard for the recitations of claims under examination.

Reconsideration and an early allowance are respectfully solicited.

Respectfully submitted,

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